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bear caution statement as follows: Inadequate mixing (recirculation or agitation), of liquid Type B feeds has resulted in increased monensin concentration which could be fatal to goats.

(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(6)(i)(b)(1) of this section. A manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing an NADA for the product or by establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish positional stability; and (iii) requesting No. 000986 in §510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the FEDERAL REGISTER because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(6)(i)(b)(1) of this section may also follow this procedure.

(ii) [Reserved]

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting \$558.355, see the List of CFR Sections Affected in the Finding Aids section of this volume.

## $\S 558.360$ Morantel tartrate.

(a) Approvals. Type A medicated articles: 88 grams per pound to 000069 in  $\S510.600(c)$  of this chapter.

- (b) Related tolerances. See §556.425 of this chapter.
- (c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.
- (2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.
- (d) Conditions of use—(1) Amount. 0.44 to 4.4 grams of morantel tartrate per pound of feed.
- (2) Indications for use—(i) Cattle. For removal and control of mature gastro-intestinal nematode infections of cattle including stomach worms (Haemonchus spp., Ostertagia spp., Trichostrongylus spp.), worms of the small intestine (Cooperia spp., Trichostrongylus spp., Nematodirus spp.), and worms of the large intestine (Oesophagostomum radiatum).
- (ii) Goats. For removal and control of mature gastrointestinal nematode infections of goats including Haemonchus contortus, Ostertagia (Teladorsagia) circumcincta, and Trichostrongylus axei.
- (3) Limitations. Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter; do not treat goats within 30 days of slaughter.

[46 FR 50950, Oct. 16, 1981, as amended at 47 FR 53352, Nov. 26, 1982; 51 FR 7399, Mar. 3, 1986; 51 FR 9005, Mar. 17, 1986; 52 FR 11642, Apr. 10, 1987; 59 FR 17922, Apr. 15, 1994]

## §558.363 Narasin.

- (a) Approvals. Type A medicated articles containing specified levels of narasin approved for sponsors identified in §510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:
- (1) To 000986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.
- (2) To 000986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.

- (3) To 000986: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.
- (4) To 012799: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambermycins, paragraph (d)(1)(iv) of this section.
- (5) To 012799: 45 grams per pound, with 4 and 10 grams per pound bambermycins, and 45.4, 90, and 227 grams per pound roxarsone, paragraph (d)(1)(vii) of this section.
- (b) *Tolerances*. See §556.428 of this chapter.
  - (c) [Reserved]
- (d) *Conditions of use.* It is used as follows:
- (1) Broiler chickens—(i) Amount per ton. Narasin, 54 to 72 grams.
- (A) Indications for use. For prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.
- (B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.
- (ii) Amount per ton. Narasin, 54 to 72 grams, plus roxarsone 45.4 grams (0.005 percent).
- (A) *Indications for use.* For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati* including some field strains of *E. tenella* which are more susceptible to roxarsone combined with narasin than to narasin alone.
- (B) *Limitations.* For broiler chickens only; feed continuously as the sole ration; do not feed to laying chickens; may be fatal if accidentally fed to adult turkeys or to horses; withdraw 5 days before slaughter; as sole source of organic arsenic; not approved for use with pellet binders.
- (iii) Amount per ton. Narasin, 27 to 45 grams, plus nicarbazin, 27 to 45 grams.
- (A) Indications for use. For the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.
- (B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other

- equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Withdraw 5 days before slaughter. The 2 drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 000986 in §510.600(c) of this chapter may be used in the combination.
- (iv) *Amount per ton.* Narasin, 54 to 72 grams, plus bambermycins, 1 to 2 grams.
- (A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.
- (B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. May be fatal if fed to adult turkeys, horses, or other equines.
- (v) Amount per ton. Narasin 54 to 72 grams, roxarsone 22.7 to 45.4 grams, and bacitracin methylene disalicylate 10 to 50 grams.
- (A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, for increased rate of weight gain, and for improved feed efficiency.
- (B) Limitations. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Drug overdose or lack of water may result in leg weakness. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by roxarsone by 046573, bacitracin methylene disalicylate by 046573 in §510.600(c) of this chapter.
- (vi) Amount per ton. Narasin 54 to 72 grams, and bacitracin methylene disalicylate 10 to 50 grams.
- (A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*, *E. necatrix*, and *E. tenella*, for increased rate of weight gain, and for improved feed efficiency.
- (B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other

equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin methylene disalicy-late by 046573 in §510.600(c) of this chapter.

(vii) *Amount per ton.* Narasin 54 to 72 grams, bambermycins 1 to 2 grams, and roxarsone 22.7 to 45.4 grams.

- (A) Indications for use. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima, and E. brunetti, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.
- (B) Limitations. For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys or horses or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Narasin as provided by 000986 in §510.600(c) of this chapter, bambermycins by 012799, and roxarsone by 046573.

(2) [Reserved]

[51 FR 29098, Aug. 14, 1986, as amended at 53 FR 24260, June 28, 1988; 54 FR 1928, Jan. 18, 1989; 54 FR 5930, Feb. 7, 1989; 54 FR 9430, Mar. 7, 1989; 54 FR 29335, July 12, 1989; 55 FR 8460, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 57 FR 32176, July 21, 1992; 63 FR 13124, Mar. 18, 1998]

## § 558.365 Nequinate.

- (a) Approvals. Type A medicated articles: 4 percent to 017800 in  $\S510.600(c)$  of this chapter.
- (b) Related tolerances. See §556.440 of this chapter.
- (c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.
- (d) Conditions of use. It is used as follows:
- (1) Broiler or fryer chickens—(i) Amount per ton. Nequinate, 18.16 grams.
- (a) Indications for use. An aid in the prevention of coccidiosis caused by E.

tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati.

- (b) Limitations. Feed continuously as the sole ration.
- (ii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus roxarsone, 45.4 grams (0.005 percent).
- (a) Indications for use. An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, and *E. mivati*; growth promotion and feed efficiency; for improving pigmentation.
- (b) Limitations. Feed continuously as sole ration throughout the starting period; withdraw 5 days before slaughter; as sole source of organic arsenic.
- (iii) Amount per ton. Nequinate, 18.16 grams (0.002 percent) plus oxytetracycline, 200 grams.
- (a) Indications for use. For control of complicated chronic respiratory disease (air-sac infection), infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).
- (b) Limitations. As monoalkyl  $(C_8-C_{18})$  trimethylammonium oxytetracycline as provided by No. 000069 in \$510.600(c) of this chapter.
- (2) Roaster chickens or replacement chickens for caged layers—(i) Amount per ton. Nequinate, 18.16 grams (0.002 percent).
- (ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and <i>E. mivati.*
- (iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2685, Jan. 26, 1987]

## §558.366 Nicarbazin.

- (a) Type A medicated articles: 25 percent to 000986, 060728, and 063271 in \$510.600(c) of this chapter for use as indicated in the table in paragraph (c) of this section.
- (b) Related tolerances. See §556.445 of this chapter.
- (c) *Conditons of use.* It is used in chicken feed as follows: